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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/301,766	04/29/1999	EIJIRO WATANABE	0020-4559P	6045

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EXAMINER

KRUSE, DAVID H

ART UNIT	PAPER NUMBER
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1638

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DATE MAILED: 08/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/301,766

Applicant(s)

WATANABE ET AL.

Examiner

David H Kruse

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 16-23 and 28-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 16-23 and 28-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR § 1.114, including the fee set forth in 37 CFR § 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR § 1.114, and the fee set forth in 37 CFR § 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR § 1.114. Applicant's submission filed on 20 May 2003 has been entered.
2. The preliminary amendment filed 20 May 2003 has been entered.
3. Those rejections not specifically addressed in this Office action are withdrawn in view of Applicant's amendments and/or argument.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 101

5. 35 U.S.C. § 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 1-10, 16-23 and 28-30 are rejected under 35 U.S.C. § 101 because the claimed invention is not supported by either a substantial asserted utility or a well-established utility.

This rejection had previously been withdrawn in the Office Action mailed 20 November 2002, but the Examiner has discovered new art that brings into question a

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substantial or a well-established utility of the claimed invention and so this rejection is reiterated as previously stated in the Office Action mailed 6 February 2002.

The specification discloses nucleic acid sequences that encode putative raffinose synthase enzymes (SEQ ID Nos. 2, 4, 6 and 8). The specification asserts that these nucleic acid sequences encode raffinose synthase (page 8 of the Specification). However, Applicant has provided no evidence to substantiate the assertion that the encoded proteins function as raffinose synthase. There are no working examples to demonstrate what specific function the encoded polypeptides will have upon expression in a transgenic host cell. Applicant has only provided examples of transforming a plant with a nucleic acid that encodes a putative *Brassica* raffinose synthase enzyme, but provides no evidence of function in the transformed plant (see for example, Example 9 on pages 49-51 of the specification). The art teaches that one of skill in the art cannot assume the function of the polypeptide encoded by an isolated nucleic acid solely based on sequence similarity to a known polypeptide sequence (see Duggleby 1997, previously cited, and Richmond *et al* 2000, Plant Physiology 124: 495-498, see paragraph spanning left and right column on page 497). In addition, the art teaches that raffinose synthase enzymes have high overall amino acid sequence homology with seed imbibition proteins and stachyose synthases, hence amino acid sequence similarity cannot be used to assert function (see Peterbauer *et al* 2002, Planta 215:839-846, see page 840, left column and page 841, right column).

Consequently, Applicant has failed to define a substantial utility for the claimed nucleic acids, hence, a well-established utility is not known.

Claim Rejections - 35 USC § 112

7. Claims 1-10, 16-23 and 28-30 are rejected under 35 U.S.C. § 112, first paragraph. Specifically, since the claimed invention is not supported by either a substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

8. Claims 1, 16-23 and 28-30 remain rejected and claims 2-10 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 20 November 2002. Applicant's amendment filed 20 May 2003 does not present any arguments to this rejection.

The teachings of Peterbauer *et al* 2002 are outlined above. The art teaches that one of skill in the art cannot describe a raffinose synthase, or the nucleic acid that encodes it, based on amino acid sequence similarity with a known raffinose synthase. Hence, it remains unclear that Applicant has actually describes any nucleic acids that encode a raffinose synthase. If Applicant is able to provide evidence of function of the describe nucleic acids, then it is the Examiner's opinion that the description of such nuclei acid does not adequately describe other nucleic acids that hybridize to said sequences as broadly claimed in claims 1 and 30.

See, MPEP § 2163 which states that the claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of

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its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

9. Claims 1-10, 16-23 and 28-30 remain rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 20 November 2002. Applicant's amendment filed 20 May 2003 does not present any arguments to this rejection.

The art teaches that one of skill in the art cannot assume the function of the polypeptide encoded by an isolated nucleic acid solely based on sequence similarity to a known polypeptide sequence (see Duggleby 1997, previously cited, and Richmond *et al* 2000, Plant Physiology 124: 495-498, see paragraph spanning right and left column on page 497). In addition, the art teaches that raffinose synthase enzymes have high overall amino acid sequence homology with seed imbibition proteins and stachyose synthases, hence amino acid sequence similarity cannot be used to assert function (see Peterbauer *et al* 2002, Planta 215:839-846, see page 840, left column and page 841, right column). Hence, it would have required undue trial and error experimentation by

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one of skill in the art at the time of Applicant's invention to make and use the genus of nucleic acids claimed and to isolate others within the scope of claims 1 and 30, and confirm their function in order to make and use the claimed vectors and transgenic organisms.

10. Claims 1, 16-23 and 28-30 remain rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

At claim 1, subsections (i), (j) and (k), the terms "obtainable", "hybridizable" and "amplifiable" render the claim indefinite because the terms are indefinite limitations and do not state the metes and bounds of the claimed invention. Claims 16-23, 28 and 29 are indefinite because they do not obviate the indefiniteness of said terms in claim 1.

At claim 30, subsections (i), (j) and (k), the terms "obtainable", "hybridizable" and "amplifiable" render the claim indefinite because the terms are indefinite limitations that do not state the metes and bounds of the claimed invention.

Conclusion

11. The claims are free of the prior art, which neither teaches nor suggests the claimed isolated nucleic acids encoding a raffinose synthase enzyme. The rejection under 35 USC § 102(e) over Osumi *et al* (US Patent 6,166,292) is withdrawn in view of *In re Hilmer, Korger, Weyer, and Aumuller*, 149 USPQ 480 (CCPA 1966).

12. No claims are allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (703)

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306-4539. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (703) 306-3218. The fax telephone number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (703) 308-0196.

A handwritten signature in black ink, appearing to read "David H. Kruse". The signature is fluid and cursive, with a large initial "D" and "K".

David H. Kruse, Ph.D.
7 August 2003